

# **NTP Update**

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NTP Board of Scientific Counselors Meeting December 1, 2006



## NTP Research and Testing Program

- Cellular phone radio-frequency emissions
- Contaminants in drinking water
- DNA therapies
- Endocrine disruptors
- Herbals and dietary supplements
- Nanoscale materials
- Occupational exposures
- Perfluorinated compounds
- Photoactive compounds
- Polybrominated flame retardants



# NTP Testing Program (FY2006)

Types of Studies	Number of studies
Studies started	
Chronic studies	7
Subchronic studies	23
Immunotoxicity studies	5
Genetic toxicity studies	46
Studies completed	
Chronic studies	4
Genetically modified models	5
Subchronic studies	10
Immunotoxicity studies	6
Reproductive toxicity studies	1
Genetic toxicity studies	90

# NTP Reports Published (FY2006)

Type of Reports	Number
NTP Technical Reports	7
NTP Toxicity Reports	2
Genetically Modified Models Reports	6
NTP-CERHR Monographs	1
NICEATM Current Status of Methods for Identifying Ocular Corrosives and Severe Irritants	4

## **Use of NTP Reports**

### **Type of Report**

NTP-CERHR monographs on phthalates

NTP technical reports on dioxin and PCBs

Safety and biodistribution study in rodents of recombinant retrovirus encoding human aquaporin-1 cDNA

#### Use

Support addition to California Proposition 65's list of reproductive toxicants

**EPA** used information for inclusion of chemicals in the VCCEP program

Used in WHO review of the toxic equivalency factor approach for dioxin risk assessment

Data support moving forward with clinical trial of a novel gene therapy for salivary gland hypofunction

## **NTP Roadmap Workshops**

- Strains and stocks: Should we switch? June 16-17, 2005
- High Throughput Screening Assays, December 14-15, 2005
- Hormonally-Induced Reproductive Tumors:
  Relevance of Rodent Bioassays, May 22-24, 2006
- Biomarkers for Toxicology Studies, September 20-21, 2006

## **Report on Carcinogens**

- Proposed review process for nominations to 12<sup>th</sup> RoC
  - Public peer review of draft background documents by ad hoc scientific expert panels.
  - Peer review of draft substance profiles by BSC.
  - Greater transparency, increased expert review.
- NTP sent proposed process to NTP Executive Committee, Interagency Scientific Review Group (ISRG), and NIEHS/NTP Scientific Review Group (NSRG).
- OMB sent proposed process to CENR Toxics and Risk Subcommittee and IRIS process review group.
- <u>Federal Register</u> notice and comments Aug-Sept 2006.
  - Comments from 6 industry groups.
- Next step: NTP submits to OMB thru HHS. OMB has 30 days to review.

## Center for Evaluation of Risks to Human Reproduction

- Soy Formula and Genistein
  - Expert panel meetings March 2006.
  - Draft NTP briefs available for public comment through December 8.
- Hydroxyurea
  - Draft Expert Panel Report available for public comment through December 15.
  - Expert panel meeting January 24-26, 2007.
- Bisphenol A
  - Draft Expert Panel Report to be released for public comment on December 15.
  - Expert panel meeting March 5-7, 2007.

# NTP Interagency Center for Evaluation of Alternative Toxicological Methods

- Mouse LD50 assay for botulinum toxin testing
  - Workshop November 2006.
  - In vitro methods promising, but development/validation still needed.
- Acute oral systemic toxicity testing
  - Peer review panel May 2006.
  - Test method recommendations to be forwarded to federal agencies.
  - In vitro cytotoxicity test methods not sufficiently accurate to predict regulatory hazard categories, but may determine starting doses for in vivo protocols.
- Ocular toxicity testing
  - Peer review panels (2) in 2005.
  - Test method recommendations to be forwarded to federal agencies.
  - In vitro methods may be an appropriate alternative and should be considered prior to conducting in vivo ocular testing.
- Develop 5-year plan
  - Soliciting public comments (<a href="http://iccvam.niehs.nih.gov/docs/5yearplan.htm">http://iccvam.niehs.nih.gov/docs/5yearplan.htm</a>).
  - Due November 2007.